Clinical Study Summary

DEV/CCM/02883.2007

CT Registry ID#: NCT00630630 **Study No.: N01088**		
These results are supplied for information purposes only. Prescribing decisions should be made based on the approved package insert.		
Based on Clinical Study Report document reference code: RRCE06B0832		
Proprietary Drug Name Keppra®Tablets	**INN** Levetiracetam	**Therapeutic area and indication(s)** Epilepsy
Name of Sponsor/Company: UCB		
Title of Study: A multicenter, double-blind, placebo-controlled, parallel-group study of the safety and efficacy of levetiracetam in the adjunctive treatment of adult female subjects (aged 18 to 40 years) with C1 catamenial epilepsy		
Investigator(s) (number only): 8		
Study Center(s) (number only): 8		
Length of Study: Date first patient enrolled: 18-Nov-2002 Date last patient completed: 14-Nov-2003	Phase of Development: Phase IV	

Abstract:
Study objectives were to determine the percent change from baseline in catamenial seizure (SZ) frequency with levetiracetam (LEV) dosing increased from 1000 mg/day to 3000 mg/day compared to placebo (PBO) during the peri-menstrual period in female subjects aged 18 to 40 years with catamenial epilepsy. Secondary efficacy variables were: the number of subjects who achieved at least a 50% reduction in SZ from baseline (responder rate); the number of days free from SZ per week during the catamenial period, the increased dosing period, and overall; the ratio of catamenial SZ frequency to non-catamenial SZ frequency; and the catamenial SZ frequency during ovulatory and anovulatory cycles. Safety was assessed through vital signs, laboratory test results, and adverse event (AE) reporting, as well as physical and neurological examinations.

Publication Reference(s) based on the study:
None

Number of Patients:			
Planned, N:	**130**		
Enrolled, N:	**3**		
Completed, n (%):	**Not applicable**		
Demography:	**PBO**	**LEV**	**LEV**
Caucasian female subjects, subject number	**012/002**	**014/001**	**015/001**
Age (years)	20.7	36.0	29.8

Safety Outcomes:
Summary of treatment emergent adverse events , deaths, other serious adverse events (SAEs) and certain other significant adverse events: There were no deaths, SAEs or AEs leading to premature discontinuation during the study. No AEs were reported in the PBO-treated subject (012/002). One subject (014/001) experienced 3 AEs; 2 of moderate intensity and 1 of mild intensity. One AE (hangover feeling) was considered possibly related to the study drug. The remaining subject (015/001) experienced 5 AEs of mild intensity. One AE (mood swings) was considered possibly related to the study drug.

Treatment Emergent AEs:	**PBO 012/002**	**LEV 014/001**	**LEV 015/001**
Total number of reported TEAEs	**0**	**3**	**5**

CT Registry ID#: NCT00630630 **Study No.: N01088**			
TEAEs by Primary System Organ Class	*n [n considered drug-related by the Investigator]*		
General disorders and administration	**0**	**1 [1]**	**0**
Immune system disorders	**0**	**0**	**1**
Infections and infestations	**0**	**1**	**3**
Nervous system disorders	**0**	**1**	**0**
Psychiatric disorders	**0**	**0**	**1 [1]**
Death, SAEs, and Other SAEs:			
Death, n (%):	**0**		
Patients with SAEs, n (%):	**0**		
Primary & Secondary Outcomes: The study was stopped prematurely, therefore data related to the primary endpoint and secondary efficacy endpoints were not analyzed.			